Buprenorphine Guidelines for Opioid Treatment Programs
State of New Jersey – Division of Addiction Services

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INTRODUCTION

The FDA approved the use of buprenorphine, in the form of **Suboxone and Subutex**, for the treatment of opiate dependence on October 8, 2002 for ***medical maintenance and medically supervised withdrawal.*** Buprenorphine is a partial agonist that is available for use solely by physicians certified in Addiction Medicine and those who have satisfied qualifications set-forth under the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000). On **May 22, 2003, SAMHSA announced an interim final rule permitting Opioid Treatment Programs (OTPs) serving individuals addicted to opioids to offer buprenorphine treatment** along with methadone**.** The rule enables OTPs that are certified by SAMHSA to provide **Subutex and Suboxone for opioid maintenance or detoxification** treatment.

The provision of opioid addiction treatment with Subutex and Suboxone in SAMHSA certified OTPs ***does not require a DATA 2000 waiver***. Additionally, such treatment is ***not subject to the 30 and 100 patient limit*** that applies to individual physicians and group practices providing opioid addiction treatment outside the OTP system under the authority of a DATA 2000 waiver. The provision of opioid addiction treatment with Subutex and Suboxone in treatment settings other than OTPs, even BY physicians who are licensed to work in OTPs, does require a DATA 2000 waiver and is subject to the 30 and 100 patient limits for individual and group practices.

OTPs providing Subutex and Suboxone for opioid maintenance and detoxification **must conform to the Federal opioid treatment standards set forth under 42 C.F.R. 8.12.** These regulations require that OTPs provide medical, counseling, drug abuse testing, and other services to patients admitted to treatment. To offer Subutex and Suboxone, **OTPs need to modify their registration with the DEA to add Schedule III narcotics to their registration certificates.** OTPs can initiate this process by fax or letter. The letter should include the OTPs DEA registration number and request that the registration be amended to list Schedule III narcotic drugs. The letter must be signed by the program director or the medical director. Further information about this process can be obtained on the DEA Drug Registration Web site at: ***http://www.deadiversion.usdoj.gov/drugreg/change_requests/sched_change.htm***.

Once the registration has been modified, **OTPs can order** Subutex and Suboxone directly from Reckitt Benckiser **for dispensing** by calling 1-877-782-6966 or **patients can be provided with prescriptions** for their medication.

While there are some current federal guidelines for use and the practice of opiate treatment, the State of New Jersey's Division of Addiction Services (DAS) seeks to provide modified details and guidelines for use and practice in New Jersey. These guidelines are meant to enhance the existing federal guidelines. These guidelines are specific for the use of buprenorphine in OTPs. ***Injectable buprenorphine is not approved for the treatment of opiate dependence.***

Primary and Aftercare Counseling

Substance abuse treatment providers need to accept ***buprenorphine therapy as adjunctive to addiction treatment, just as OTPs accept methadone treatment as adjunctive*** and not contrary to the concept of effective treatment for opioid dependence**.** Treatment professionals will need **initial and ongoing education** to effect this significant change in treatment philosophy. Those patients who are receiving buprenorphine therapy *should not be in segregated groups.* Currently those individuals in treatment with co-occurring disorders are not routinely segregated for primary and continuing care therapy, and those patients receiving buprenorphine should not be segregated either. ***Patients on Suboxone or Subutex should be permitted to participate alongside patients on methadone as well as patients not receiving any therapy in primary and aftercare substance abuse counseling.***

Patient Assessments

Screening Tools

All patients admitted to an OTP need to meet the established admission criteria as per the Federal regulations for OTPs. All patients must meet **DSM-IV-TR** criteria for **Opiate Abuse or Dependence.** Those persons presenting for substance abuse treatment must undergo a screening process to determine their diagnosis, severity of illness, and the selection of the appropriate level of care for rehabilitation counseling. The American Society of Addiction Medicine Patient Placement Criteria-2 (**ASAM PPC-2**) is the only peer reviewed beta instrument currently available for patient placement assessment. OTPs should select and use consistently a screening tool for each and every patient (e.g. **CAGE; COWS; CAGE-AID; or Narcotic Withdrawal Scale).**

Complete History and Physical Examination

All patients admitted to an OTP will undergo a complete history and physical examination. The history should include drug and alcohol use, psychiatric, past legal, medical, surgical, family, and previous drug treatment. The physical examination should be comprehensive and be specific for signs of addiction. In addition, patients should undergo a neurological and mental status. **All patients that are to be treated with Subutex or Suboxone must meet DSM-IV-TR criteria for Opioid abuse or dependence. All patients must meet ASAM PPC-2 criteria for level I or level II treatment.**

Comprehensive Patient Management and Referrals

All patients must be referred for follow-up of primary medical conditions not being addressed in the OTP to primary care or other medical specialists as may be warranted.

All patients with major psychiatric diagnoses must be referred to a Psychiatrist, or licensed mental health facility, qualified to manage patients with addictions.

Detoxification

Many patients who entered into treatment for opiate dependence are fearful that they will not receive the appropriate care and will be left to suffer moderate to severe withdrawal symptoms. Therefore, many patients that present for treatment have used an opiate just prior to their arrival. The use of buprenorphine prematurely can induce withdrawal as it is also a partial agonist. ***It is important to instruct the patients that they do not use any opiates at least twelve hours before they arrive.***

Detoxification is a two-step process, **stabilization** (the amelioration of signs and symptoms of withdrawal) followed by a **tapering** of the medication to zero. The stabilization dose varies from person to person. Some patients are stabilized with as little as 8 mg and others require the maximum dose of 32 mg. Patients can be detoxified (tapered) once stabilized via a **"moderate-period"** reduction rate of **2 mg every two to three days.** Therefore a patient stabilized on 32 mg may need two to three weeks to successfully taper to zero. Some patients may need to taper more slowly via the **"long-period"** reduction which could occur over many **weeks and months**. *Patient selection for "moderate versus long" withdrawal detoxification is crucial.* Some patients may require a slower detoxification occurring over a number of weeks and other patients may require maintenance therapy with buprenorphine. *For those patients that cannot be stabilized or withdrawn from buprenorphine on an outpatient basis, these cases may need to be referred for inpatient residential treatment.* In all cases, **all patients must be engaged in rehabilitative counseling** for support and to move into the later stages of addiction treatment and sustained recovery.

Subutex is the *formulation of choice* for detoxification in the *inpatient* setting. Subutex is buprenorphine without naloxone and is therefore less likely to induce a withdrawal syndrome in patients that are still under the influence of some opiate.

Suboxone is the *formulation of choice for use in outpatient detoxification* settings. Suboxone is buprenorphine formulated with naloxone which provides added protection and deterrence from using unauthorized opiates which is assumed to be a greater risk in outpatient settings. Buprenorphine, when prescribed appropriately, is very effective in stabilizing opiate withdrawal symptoms without initiating or worsening withdrawal symptomatology in appropriately prepared patients.

Once the patient has begun or completed detoxification, he or she is ready for primary substance abuse counseling. See **CSAT TIP #40 & #43 for details.**

Buprenorphine Maintenance

Buprenorphine is FDA approved for the maintenance therapy of opioid dependent patients. Patients can be induced, according to protocols established in CSAT TIP #40. It is very important to induce and stabilize the patient as soon as possible in order to avoid patient drop outs. It is suggested that patients are stabilized as rapidly as possible and that they are engaged in rehabilitative counseling. Patients may require maintenance dosages that range from less than 2 mg up to 32 mg. daily. The maintenance dose can be established in most patients in 7 to 10

days. **Once the maintenance dose** is established, OTPs should begin to provide **"take home" medication or prescriptions** for buprenorphine to those patients that are otherwise stable and compliant with the OTPs rules and regulations (participate in all scheduled counseling appointments, all "negative" urine drug tests). The following schedule for "take home" medication and prescriptions has been used:

1. One month stable and compliant … 1 week supply
2. Two months stable and compliant … 2 weeks supply
3. Three months stable and compliant … 3 weeks supply
4. Four months stable and compliant …. 4 weeks supply

If a patient relapses or becomes noncompliant with treatment plan the "take home" or prescription privilege become modified as necessary to better engage the patient in treatment, including but not limited to, intensification of individual and/or group counseling services and reassessment for appropriate level of care.

Buprenorphine Discontinuation

When the decision is made to discontinue the buprenorphine, it should a "joint decision" between the patient and the physician. The daily dose should be reduced by an amount predetermined by the patient and physician over a predetermined period of time. Discontinuance can be performed over a few days in an emergent situation but **it is preferable that discontinuation occur over a longer period of time.**

Agency Policies and Procedures

Substance abuse facilities licensed by DAS to provide OTP that wish to administer buprenorphine are required to submit policies and procedures regarding dispensing and storage of this Schedule III narcotic to DAS.

TREATMENT PROTOCOLS

DETOXIFICATION … Clinical Guidelines CSAT TIP #40

INDUCTION …….. Clinical Guidelines CSAT TIP # 40

MAINTENANCE …….. Clinical Guidelines CSAT TIP # 40

DISCONTINUATION … Clinical Guidelines CSAT TIP # 40

SPECIAL POPULATIONS

Buprenorphine and Pregnancy

Currently, *methadone is still the pharmacotherapy of choice* for the treatment of opiate dependent pregnant patients. Patients should be offered referral to a methadone provider for care. If the patient, however, refuses or has misgivings about methadone, buprenorphine has been used successfully. The FDA classifies buprenorphine as a Category C drug. The risks of Category C drugs must be explained to the patient and thereafter can be used with **informed consent**. Buprenorphine use in pregnancy needs to be further evaluated by controlled studies. To date, the safety has been determined by case series reports. **The discussion and informed consent should be clearly documented in the patient's chart. Subutex is the formulation of choice.**

Buprenorphine Maintenance and Pain Management

Acute Pain

Patients that are on buprenorphine maintenance and who are experiencing *acute pain* should attempt to manage the pain with *non-narcotic medications* in combination with their prescribed buprenorphine. Buprenorphine has analgesic properties and can be an effective analgesic. The dose of buprenorphine can be increased to try to improve the analgesia, in conjunction with non-narcotic analgesics. **Patients in whom the pain is not relieved should undergo aggressive treatment with narcotic analgesics.** The buprenorphine should be discontinued while the appropriate opiate analgesic is employed to address the acute pain. Once the acute pain has been successfully managed, the buprenorphine should be restarted.

Chronic Pain

Opiate dependent patients with *chronic pain are usually not good candidates* for buprenorphine therapy because of the analgesic "ceiling effect". These patients fair better with long acting narcotic analgesics. Methadone has proven to be an effective choice.